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PELVIC FLOOR MUSCLE TRAINING VERSUS NO TREATMENT OR INACTIVE CONTROL TREATMENTS FOR URINARY INCONTINENCE IN WOMEN: A COCHRANE REVIEW UPDATE

Hypothesis / aims of study

The objective of this study is to determine the effectiveness of pelvic floor muscle (PFM) training in the management of female urinary incontinence (UI). The following hypothesis was tested: that PFM training is better than no treatment, placebo, sham, or any other form of inactive control treatment. Because new trials are eligible for inclusion in the Cochrane systematic review (last updated 2014) [1], an update of current best evidence is needed.

Study design, materials and methods

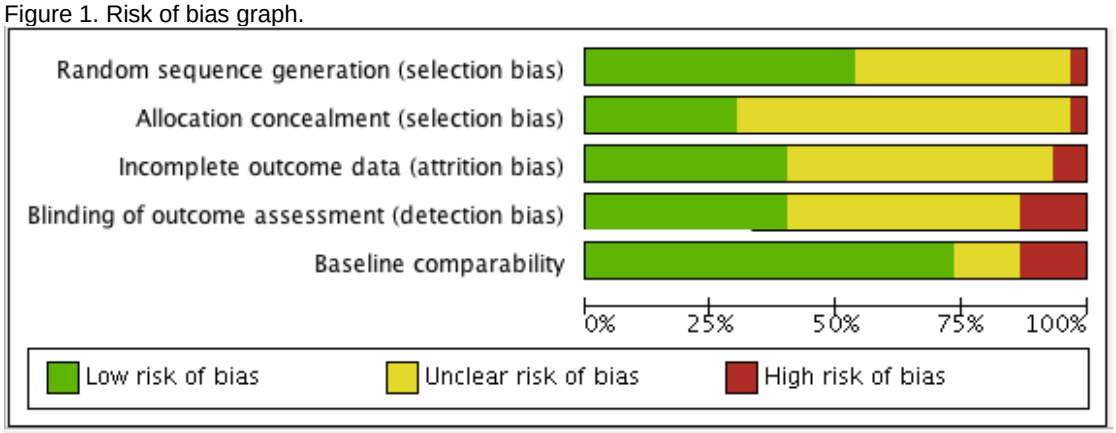
We searched (17 March 2017) the Cochrane Incontinence Group Specialised Register, which contain: trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE and MEDLINE in process; hand searched journals and conference proceedings; and the reference lists of relevant articles. We included randomised or quasi-randomised trials in women with stress (SUI), urge (UUI) or mixed urinary incontinence (MUI), based on symptoms, signs, or urodynamics. One arm of the trial included PFM training. The comparator arm was no treatment, placebo, sham, or other inactive control treatment. Trials were sub-grouped by UI types. Outcomes of interest were patient reported measures, clinician reported measures, quality of life (QOL) and side effects. Two reviewers (LC and CD) independently assessed eligibility and methodological quality of trials. Any disagreement was resolved by discussion or arbitration with a third party (JHS). Two reviewers independently extracted data for the pre-defined outcomes (LC and CD). Meta-analysis was conducted when appropriate, in subgroups (by UI type), due to the heterogeneity of samples. For categorical outcomes we used risk ratio (RR) and for continuous outcomes we determined a mean difference, both with 95% confidence intervals (CI). A fixed effect model was used except if there was statistically significant heterogeneity in which case a random-effects model was considered. Risk of bias assessment was carried out as described in the Cochrane Handbook [2].

Results

Nine new trials were added in the update. In total, thirty trials involving 1788 women (918 PFM training, 870 controls) were included in the review; 26 trials (1526 women) contributed data to the meta-analysis. The trials were generally of small or moderate size and many were at moderate risk of bias, based on the trial reports. Risk of bias assessment showed that across all studies approximately 55% of trials had adequate random sequence generation and 30% had adequate allocation concealment. In 40% of trials there was low risk for attrition bias, and outcome assessors were adequately blinded. 75% of trials presented adequate baseline comparability (Figure 1).

Fourteen countries contributed studies to this review (USA, Brazil, UK, Japan, Turkey, Canada, Norway, Austria, China, Iran, Korea, Portugal, The Netherland, and Sweden). There was considerable variation in: interventions used (e.g., programs lasting from 1 to 24 weeks, with 8 to 500 PFM voluntary contractions per day); study populations (e.g., pre- and post-menopausal women, women with osteoporosis and also young volleyball athletes); and outcome measures (e.g., patient reported cure or improvement of symptoms, satisfaction, quantification of symptoms, specific and non specific QOL questionnaires, adverse effects, measures of PFM function and of adherence, among others). For the first time there were trials that reported on women with mixed UI only (n=1) and urge UI only (n=1), and trials that presented an intervention provided exclusively by a smartphone app (n=1).

Figure 1. Risk of bias graph.



In women with stress UI, cure was more likely with PFM training in comparison with inactive control (4 trials, RR 8.4, 95% CI 3.7 to 19.1, p<0.00001), and cure or improvement was more likely with PFM training in comparison with inactive control (3 trials, RR 6.3, 95% CI 3.9 to 10.3, p<0.0001). For women with mixed UI, one trial reported that PFM training is associated with better quality

of life (ICIQ-UI-SF) in comparison with inactive control (MD -3.97, 95% CI -7.85 to -0.09, p<0.0001). For women with urge-predominant mixed UI one trial reported a greater reduction in the number of leakage episodes with PFM training in comparison with inactive control (MD -1.8m, 95% CI -2.7 to -1.0, p<0.0001). Finally, in trials with women with any type of UI, there was also moderate quality evidence that PFM training is associated with cure (3 trials, RR 5.5, 95% CI 2.9 to 10.5), or cure and improvement (2 trials, RR 2.4, 95% CI 1.6 to 3.5), in comparison with inactive control.

Interpretation of results

We found evidence that PFM training is better than no treatment, placebo, sham, or other inactive control treatment for women with stress UI, urge UI, mixed UI or UI of any type. The addition of nine new trials did not change the essential findings of the prior review. The wider range of populations, countries and secondary outcomes within these new trials emphasized the strength of recommendation for women with UI. Of note, in almost all new included trials, the PFM training protocols were described in more detail, with progressive training based on exercise physiology. Moreover, there were more use of patient reported symptoms and QOL outcomes, in line with recent recommendations [3].

Concluding message

Notwithstanding that long-term effectiveness of PFM training needs to be further researched, the updated review provides support for the widespread recommendation that PFM training be included as first-line conservative management programs for women with stress UI, mixed UI, urge UI and UI of any type.

References

1. Cochrane Database of Systematic Reviews 2014, Issue 5. Art. No.: CD005654
2. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0, March, 2011
3. Incontinence. 5th edition. Paris: Health Publication Ltd, 2013:389-428

Disclosures

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